

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Case No. 4:21-cv-10312

Plaintiff,

Hon. F. Kay Behm

v.

BLUEWILLOW BIOLOGICS, INC.,
et. al.

Defendants.

**PLAINTIFF TRUTEK CORPORATION'S BRIEF IN REPLY TO
DEFENDANT BLUEWILLOW BIOLOGICS, INC.'S OPPOSITION TO
PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT THAT
U.S. PATENT NO. 8,163,802 IS VALID**

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INDEX OF EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
1	The '802 Patent
2	Opening Expert Report of Dr. Amiji on Patent Invalidity
3	Deposition Testimony of Dr. Amiji
4	Responsive Expert Report of Amirali Y. Haidri, Esq.
5	USPTO Office Action
6	Responsive Expert Report of Dr. Edward A. Lemmo

I. INTRODUCTION

To date, Plaintiff, Trutek Corp. ("Trutek") and Defendant, BlueWillow Biologics, Inc. ("BlueWillow") each submitted cross-motions. Defendant submitted a motion for summary judgment that partially pled for a declaratory judgment of invalidity of the asserted claims of U.S. Patent 8,163,802 ("the '802 Patent"). This Present Motion for Partial Summary Judgment pleads the opposite, *i.e.*, for a declaratory judgment of patent validity. A copy of the '802 Patent is submitted herewith as Exhibit 1.

Defendant engaged the services of Dr. Mansoor M. Amiji as its expert to prove invalidity of the '802 Patent, and Plaintiff engaged the services of Amirali Y. Haidri, Esq. and Dr. Edward A. Lemmo as its rebuttal experts. Plaintiff's and Defendant's experts all submitted expert reports. Defendant moved to exclude the testimony of Mr. Haidri, and Plaintiff moved to exclude the testimony of Dr. Amiji specifically with respect to patent invalidity.

II. LEGAL STANDARD

Fed. R. Civ. P. 56 provides that, "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Based upon the expert reports and pleadings, there is no genuine dispute as to the material facts.

According to 35 U.S.C. § 282, the claims of the '802 Patent are valid unless Defendant can prove otherwise. While facts alleged must be viewed in a light favorable to the non-moving party, Plaintiff does not bear the burden to prove the validity of its patent. Defendant must prove invalidity by a clear and convincing evidentiary standard. *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91 (2011). Defendant has not met that burden.

Clear and convincing evidence is that weight of proof which produces in mind of the trier of fact a firm belief or conviction as to truth of the allegations sought to be established. It is evidence so clear, direct, weighty and convincing as to enable fact-finder to come to clear conviction, without hesitancy, of truth of the precise facts of case.

In re CNC Payroll, Inc., 461 B.R. 454, 461 (2013), citing *Shafer v. Army & Air Force Exch. Serv.*, 376 F.3d 386, 396 (5th Cir. 2004). See also, *In re. JMW Auto Sales*, 494 B.R. 877, 889 (2013).

III. ARGUMENT

On Page 1 of Defendant's opposition brief, Defendant asserts that, "BlueWillow intends to prove at trial and/or through its own motion for summary judgment (ECF 59) that the '802 Patent is invalid under one or more grounds." At trial, Defendant intends to rely solely on testimony from Dr. Amiji. Dr. Amiji's expert reports and deposition testimony set forth all of his opinions to date. Rebuttals to those allegations are set forth in Plaintiff's expert reports.

In Dr. Amiji's Opening Report on Invalidity (Exhibit 2), he plainly states that he is not an attorney and that Defendant's counsel merely informed him of the law.

Plaintiff does not challenge Dr. Amiji's expertise in pharmaceutical science. Yet, as is evidenced in his expert reports and his deposition testimony (Exhibit 3), Dr. Amiji is not qualified under any standard to opine on matters of law or to draw legal conclusions. Nor is he qualified to opine on the standards and procedures used by the United States Patent and Trademark Office ("USPTO").

Plaintiff's expert, Amirali Y. Haidri, Esq., submitted an expert report (Exhibit 4) in rebuttal to Dr. Amiji's allegations. Mr. Haidri received an undergraduate degree in chemical engineering and a master's degree in organic chemistry. He has experience as an organic chemist with laboratory experience. He is also a registered patent attorney practicing before the USPTO. He specializes in prosecuting chemical patents. Mr. Haidri's report (Exhibit 4) has several sub-exhibits. Exhibit A thereof is a copy of Mr. Haidri's resume. Unlike Defendant's expert, Mr. Haidri is qualified to opine on both the substance and validity of the '802 Patent.

A. Defendant's Expert Opinions are Constructed in Error Due to Dr. Amiji's Wrong Definition of a Person of Ordinary Skill in the Art.

Dr. Amiji describes his person of ordinary skill in the art ("POSA") as having *inter alia*, "at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation." (Exhibit 2, Pg. 28, ¶ 68,) This court rejected Dr. Amiji's definition (ECF 53, pp. 8-10). Instead, it adopted Plaintiff's definition

proposed by Dr. Edward A. Lemmo in his report, and specifically stated that a POSA need not possess an advanced degree. (Exhibit 6, pp. 2-6.)

Dr. Amiji is not a POSA himself, but rather a person of extraordinary skill. Yet, in his deposition, Dr. Amiji testified that he deems himself to be a person of ordinary skill. (Exhibit 3, 81:22 - 82:6.) Thus, all of Amiji's testimony is viewed through the wrong lens. He uses his own viewpoint to form the opinions presented in his report. He does not employ the perspective of an actual POSA.

On Page 10 of its Opposition Brief, Defendant states that, "Dr. Amiji is qualified to provide invalidity testimony from the perspective of a POSA." However, to provide such testimony, Dr. Amiji would need to recognize the difference between a person of ordinary skill and one of extraordinary skill.

B. Defendant's Opinions of Invalidity Based on Prior Art are in Error Because They Used the Wrong Definition of a POSA.

Dr. Amiji presented opinions alleging that the asserted claims of the '802 Patent are anticipated by a single prior art patent reference. Under 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single prior art reference." 35 U.S.C. § 102 does not require a POSA for an anticipation determination. Thus, Dr. Amiji is qualified to perform an anticipation analysis. However, he never opined that any single prior art reference taught or suggested every element in the asserted claims. He merely presented conclusory opinions.

Next, Dr. Amiji alleged that the asserted claims are obvious over multiple combinations of prior art references. Under 35 U.S.C. § 103, it must have been obvious to a POSA, at the time of the invention, to combine the prior art references. And, every element in the claim must be contained in said combination. One of the considerations is that the level of ordinary skill must be resolved. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). An incorrect determination as to level of skill, or an incorrect finding, may constitute reversible error if it influences the ultimate conclusion on obviousness. *Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc.*, 807 F.2d 955 (Fed. Cir. 1986). *See also Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565 (Fed. Cir. 1986).

C. Defendant's Opinion that the Claims of the '802 Patent are Directed to Ineligible Subject Matter Under 35. U.S.C. § 101 are in Error Because Dr. Amiji Misunderstands the Statute.

From Dr. Amiji's deposition testimony on eligible subject matter and credible utility under 35 U.S.C. § 101, it is apparent that he misunderstands the statute and how to apply it to the asserted claims of the '802 Patent. (Exhibit 3, pp. 31-48.)

Dr. Amiji alleges that the asserted claims of the '802 Patent are "invalid for being directed to ineligible subject matter under 35 U.S.C. § 101." (Exhibit 2, pp. 95-99.) In making this allegation, he reasons that, "[t]he '802 Patent is directed to the effects of a law of nature or a natural phenomena, namely the principle that like charges repel each other," (*Id.* at ¶ 202.) On Page 40 of Exhibit 4, Mr. Haidri stated

that a claim must be viewed as a whole to determine whether it is for a particular application and not the law of nature itself. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). All inventions utilize laws of nature in some manner.

The asserted claims of the '802 Patent do not claim electrostatic attraction or repulsion itself. Rather, they claim a process and a formulation that utilize electrostatic attraction as part of a practical multi-element application of that physical phenomenon, as required in *Diehr*. Thus, Dr. Amiji's allegations fail to prove the lack of patentable subject matter in the asserted claims.

D. Defendant's Opinion that the Claims of the '802 Patent Lack Credible Utility Under 35 U.S.C. § 101 are in Error Because Dr. Amiji Misunderstands the Utility Requirement of Section 101.

Exhibit 5 is a copy of a USPTO Office Action dated August 25, 2011 for the application that would ultimately issue as the '802 Patent. The Examiner stated:

*In reading the present specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be **inhibited** rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.¹*

(Exhibit 5 at Pg. 3.)

¹ As originally submitted, claims 1 and 2 used the word "preventing" instead of "inhibiting." In order to overcome a 35 U.S.C. § 112, First Paragraph rejection for non-enablement, Applicant amended the claims to recite "inhibiting," as suggested by the USPTO Examiner. The application was allowed to issue as a patent thereafter.

The court should take judicial notice that inhibiting infectious material from passing into the respiratory system of a person satisfies the "useful" requirement of 35 U.S.C. § 101. Thus the asserted claims exhibit credible utility.

E. Defendant's Opinions that the '802 Patent's Specification does not Comply with the Written Description and the Enablement Requirements of 35 U.S.C. § 112 are in Error.

Dr. Amiji alleges that the specification of the '802 Patent does not provide a complete written description and that it does not meet the enablement requirement of 35 U.S.C. § 112. First, in the prosecution history, the USPTO Examiner agreed that the Applicant's amendments enable the claims. (Exhibit 5, Pg. 2.) Second, Dr. Amiji alleges that the written description requirement is not met and that the disclosure is not enabled because it lacks test data and results. This is not a requirement for the disclosure of an invention. Complex patents are often issued without having been reduced to actual practice, but only to constructive practice. Dr. Amiji appears to require a manufacturing specification, instead of a written disclosure. Dr. Amiji misunderstands the requirements of Section 112.

IV. CONCLUSION

35 U.S.C. § 282 requires that the asserted claims of the '802 Patent be held valid because Defendant failed to prove their invalidity by a clear and convincing evidentiary standard. For this reason, Plaintiff's motion for partial summary judgment should be granted.

Dated: June 16, 2023

Respectfully Submitted,

/s/ Stanley H. Kremen

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A handwritten signature in black ink, appearing to read 'Keith Altman', written over a horizontal line.

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CERTIFICATE OF SERVICE

I certify that on June 16, 2023, I served the foregoing document upon all parties/counsel of record by filing copies of same using this Court's CM/ECF System.

A handwritten signature in black ink, appearing to read 'Keith Altman', written over a horizontal line.

Keith Altman, Esq.